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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/301,507

04/28/1999

MAX CYNADER

59810-3

5640

22504

7590

03/15/2005

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EXAMINER

MARTINELL, JAMES

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/301,507

Applicant(s)

CYNADER ET AL.

Examiner

James Martinell

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9/29/04 & 12/30/04.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 23-76 is/are pending in the application.  
4a) Of the above claim(s) 1-7 and 23-56 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 63-76 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 25 April 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/29/04.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

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The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1634.

Claims 1-7 and 23-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper Nos. 5 and 8.

Chen et al (Nature Genetics 1: 204 91992)) is crossed out on the form PTO-1449 submitted September 29, 2004 because it is already of record (see the form PTO-892 of September 18, 2001).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The disclosure is objected to because of the following informalities: The separate parts of Figure 5 (*i.e.*, A\_V) are not included in the Brief Description of the Drawings (page 11 of the specification). This is the basis for the objection to the drawings (see item 10 on form PTO-326 of this Office action). This objection is repeated for reasons already of record (*e.g.*, Office action mailed June 28, 2004, page 2). Applicants did not address this objection in the responses filed September 29, 2004 and December 30, 2004).

Appropriate correction is required.

Applicants' offer to submit a terminal disclaimer in connection with the obviousness double patenting rejection (see Office action mailed June 28, 2004, page 2) is acknowledged. The obviousness double patenting rejection is withdrawn because all of the claims now under examination (*i.e.*, claims 63-76) contain new matter (see below) and as claims 63-76 do not find support in the application as filed, so they do not find basis in Serial No. 10/355,716, a divisional application of the instant application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 63-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new matter in that there is no basis in the application as filed for the recitation of any particular regions of SEQ ID NO: 74 (*i.e.*, 1-50, 1-90, 1-150, and 1-155). It is noted that the full length of SEQ ID NO: 74 is 336 nucleotides (see the sequence listing). Applicants point (response filed December 30, 2004, page 10, first full paragraph) to page 16 as containing basis for the amendments. This argument is most unpersuasive. Page 16 of the application discusses total lengths of polynucleotides and not particular regions of any particular polynucleotide, let alone the specific regions of SEQ ID NO: 74 now recited in the claims.

Claims 63-76 are rejected under 35 USC § 101 because the claimed invention lacks patentable utility. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed June 28, 2004, paragraph bridging pages 2-3). Applicants' arguments response filed September 29, 2004 and December 30, 2004) are not convincing. Applicants establish the gene disclosed in Chen et al (Nature Genetics 1: 204 (1992) to be the gene associated with Norrie disease by aligning the gene of Chen et al with the gene of Kim et al (Korean J. Ophthalmology 16 (2), 93 (2002)). This argument is not sufficient to overcome this rejection because it is the application that is to establish utility. Applicants cannot rely on publications that appeared nearly a decade following the effective filing date of the application to provide a utility for the claimed invention. Furthermore, it is noted that in at least some of the fragments of SEQ ID NO: 74 that are claimed (*i.e.*, nucleotides 1-150 and 1-155), a stop codon appears at nucleotides 104-106. The presence of this stop codon would not encourage one of skill in the art to consider SEQ ID NO: 74 (at least in the reading frame in which that stop codon occurs) to be a candidate for encoding any

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polypeptide. Applicant's attempt to establish a readily apparent utility by asserting an 88% sequence identity to a candidate disease gene that is later confirmed to indeed be the disease associated gene for Norrie disease is not convincing. In *Brenner v. Manson*, Supreme Court of the U.S., 148 USPQ 689 (1966), the Court ruled that to meet the utility requirement under 35 USC § 101, an invention must provide specific benefit in its currently available (*i.e.* as of the effective filing date) form. There is nothing in the application as filed to point or lead one of skill in the art from SEQ ID NO: 74 or any particular region of SEQ ID NO: 74 to Chen et al, and thence to Norrie disease.

Claims 63-76 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed June 28, 2004, paragraph bridging pages 3-4). The discussion in the previous rejection under 35 USC § 101 is incorporated here.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. Only documents such as those intended for

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use in a personal or telephone interview should be faxed to the examiner's desktop workstation. Any Official Communication to the USPTO should be faxed to (571) 273-8300.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.

#### OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
**James Martinell, Ph.D.**  
**Primary Examiner**  
**Art Unit 1634**

3/14/05